In the Application of:

VINAY G. SAKHRANI, ET AL. DOCKET NO.: TFR-001

APPLICATION NO.: 10/791,542 GROUP ART UNIT: 1773

FILED: MARCH 2, 2004 EXAMINER: RAMSEY ZACHARIA

FOR: IMPROVED ARTICLE WITH LUBRICATED SURFACE AND METHOD

DECLARATION OF VINAY G. SAKHRANI PURSUANT TO 37 C.F.R. § 1.132

I hereby declare as follows:

1. I am the same Vinay G. Sakhrani who is a named co-inventor of Application No. 10/791,542.

2. I am a graduate of North Carolina State University with a Masters of Science degree and a background in polymer materials, plasma science, and plasma assisted CVD coatings.

3. I am employed by TriboFilm Research, Inc. as Vice-President of Technology.

4. In the Final Office Action mailed on July 12, 2006, the Examiner improperly maintained the rejection of the above referenced patent application over Williams et al. (U.S. Patent No. 4,822,632). The Examiner appears to base his rejection, in whole or in part, on the fact that the product produced using the teachings of the Williams patent appears to be either identical or only slightly different than a product produced using the teachings of the above-referenced application; that the teaching of "any pressure" in relation to the pressure at which the plasma is generated encompasses the extreme vacuum conditions of the Williams teachings as well as the atmospheric pressure conditions of the above-referenced application; and the teaching of "synthetic oils" of the Williams patent encompasses any and all synthetic oils despite the limitations in the Williams patent. However, these assertions by the Examiner are incorrect.

To obtain a better appreciation for the differences between the presently claimed method and the teachings of Williams, as well as the unexpected results and advantages flowing therefrom, the Examiner is directed to paragraph 6 below, in particular the "Analysis" section.

5. The following experiments were carried out by me or under my direct supervision and control to demonstrate the advantages of the presently claimed invention. Specifically, the following data demonstrate the advantageous properties obtained through the following differences in the teachings of Williams and the presently claimed invention: the use of a perfluoropolyether lubricant exposed to an energy source, such as a plasma at atmospheric pressure, and not a silicone-based lubricant exposed to a plasma at extreme vacuum. I conducted the experiments using a plasma at atmospheric pressure, but it is my belief based on prior experimentation that the same results would be obtained by using any suitable energy source, including but not limited to, ionizing radiation.

A. Syringes Prepared According to Example 2 of the Williams Patent

10cc polypropylene syringes barrels were coated with a 5 percent solvent solution of polydimethylsiloxane by dipping. The syringe barrels were allowed to dry at ambient conditions to evaporate the solvent. The syringe barrels were then exposed to an energy source, in this case a vacuum air plasma at the following conditions:

- Pressure in the plasma chamber – 300 millitorr
- Power – 125 watts
- Time of exposure to the plasma – 10 minutes

The syringe barrels were then assembled with unlubricated halobutyl rubber stoppers. The assembled syringes were then placed in a Harvard Apparatus syringe pump, and the force exerted by the syringe pump on the assembled syringe (that is, the force required to move the stopper in the syringe barrel) was measured using a Dillon AFG-100N digital force gauge. The travel speed was about 100 mm/min.

Figure 1 presents the results of this experiment. A very large force was required to initiate movement of the stopper (break-free force). The force required to maintain movement steadily increased until the force limit of the syringe pump was reached. This indicated that the lubricant migrated away from the barrel-stopper interface, and that the Williams teachings did not provide an adequately lubricated surface.

B. Syringes Prepared According to Applicants' Presently Claimed Method

10 cc polypropylene syringe barrels were spray coated with a perfluoropolyether lubricant (Fomblin M100® from Solvay Solexis) and exposed to an energy source, in this case a plasma at atmospheric conditions according to the claims of the presently claimed method. The syringes were then assembled with unlubricated halobutyl rubber stoppers

and tested on the same equipment used for Experiment A. Figure 2 presents the results of this experiment and show that only a very small break-free force was required to initiate movement, and that a minimal force was required to maintain movement (about $1/20^{th}$ of the force required for the syringes treated according to the Williams teachings). These surprising results are evidence of the unobviousness of applicants' presently claimed method over Williams.

C. Comparison with Perfluoropolyether Lubricant Exposed to Vacuum Plasma

In order to demonstrate the difference between using plasma generate under conditions of extreme vacuum as the energy source and plasma generated at atmospheric pressure as the energy source, 10 cc polypropylene syringe barrels coated with the perfluorpolyether lubricant were exposed to the vacuum plasma according to the parameters of Experiment A (that is, the Williams patent). These syringe barrels were then assembled with unlubricated halobutyl rubber stoppers and tested with the same apparatus as described above. The results are shown in Figure 2. While these syringes exhibited a low initial break-free force, the force needed to maintain movement steadily increased until the upper limit of the force gauge was reached. This indicated that the perfluoropolyether lubricant was not immobilized after treatment with the vacuum plasma.

D. Comparison with Perfluoropolyether Lubricant Not Exposed to Plasma

In order to further demonstrate the effect of using atmospheric plasma as the energy source in the presently claimed method, 10cc polypropylene syringe barrels were coated with the perfluoropolyether lubricant and not exposed to plasma. The lubricated barrels were then assembled with unlubricated halobutyl rubber stoppers and tested with the same apparatus as described above. The results are shown in Figure 2. The syringes exhibited extreme stick-slip phenomenon where the stopper would alternately stick then suddenly move. This is indicative of commercially available lubricated syringes and shows that the lubricant migrates from the barrel-stopper interface.

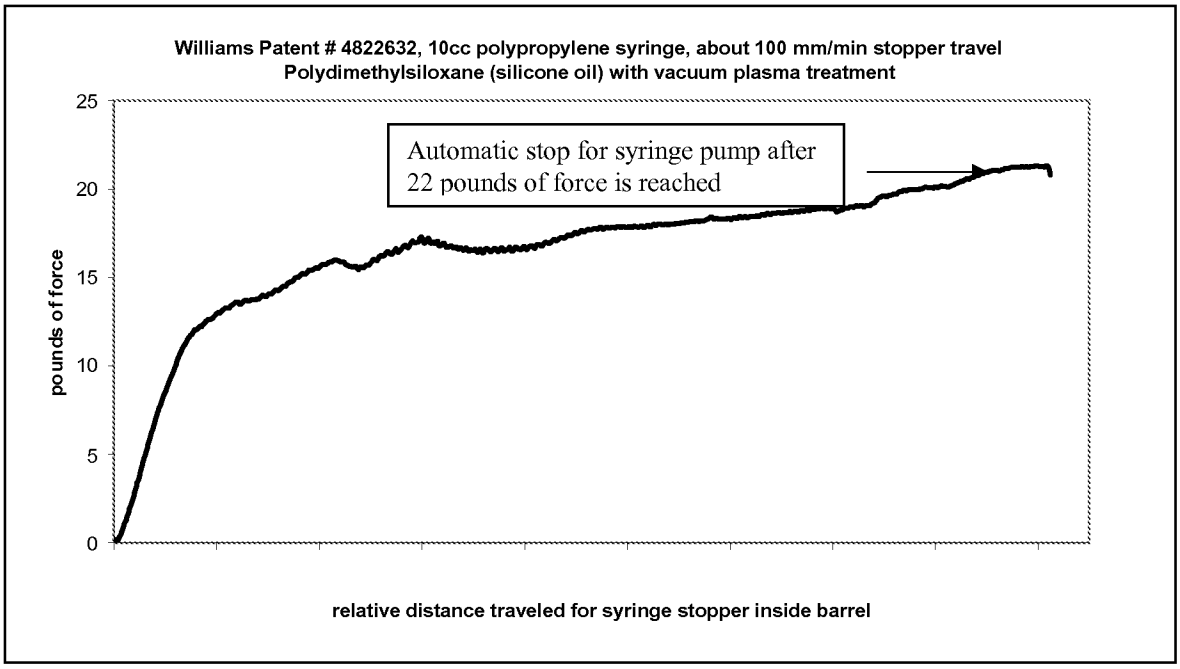

Figure 1. Silicone Lubricated Syringe with Vacuum Air Plasma Treatment. Williams et al. (U.S. Patent No. 4,822,632)

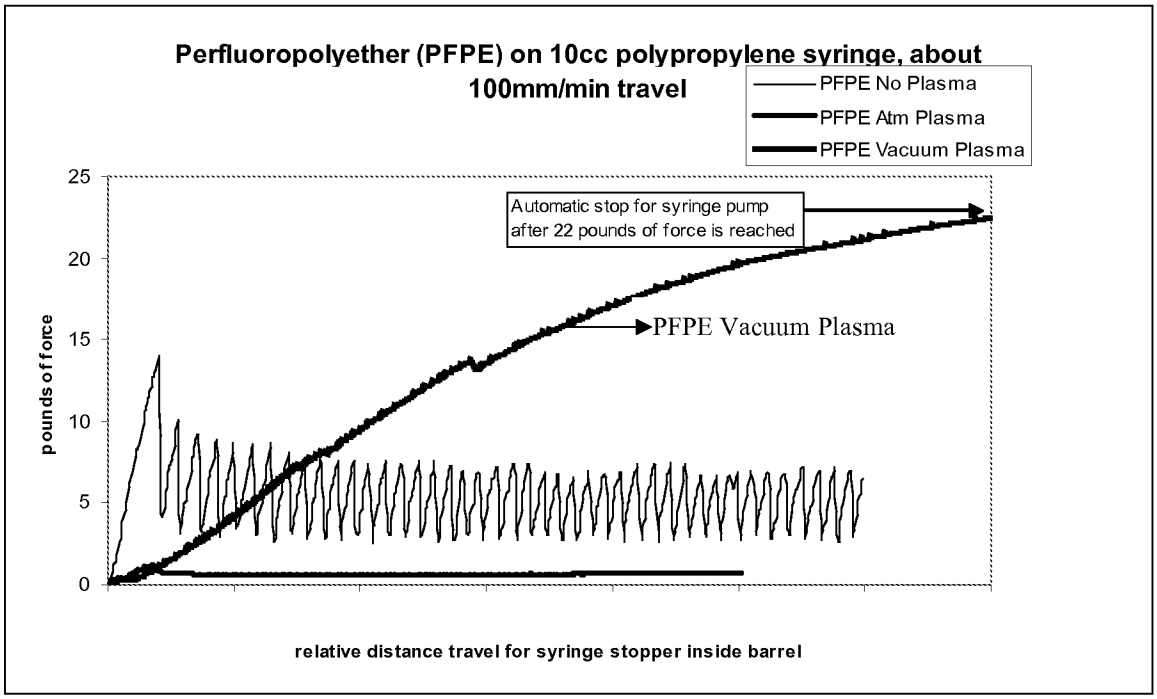

Figure 2. Comparison of Vacuum and Atmospheric Plasma Treatment Conditions for Perfluoropolyether.

6. Results

The difference in performance between the syringes prepared according to the Williams teachings and the presently claimed method provide unexpected and surprising results. It is clear from these results that the product obtained by the presently claimed method is significantly different than that produced according to the Williams teachings. The experimentation also shows that there is a significant difference between the effect produced by plasma generated under conditions of extreme vacuum and plasma generated at atmospheric pressure. Finally, the experimentation showed that all lubricants cannot be similarly classified as "synthetic oils" and the teachings of the Williams patent do not extend to perfluoropolyether compounds.

7. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing therefrom.

/Vinay G. Sakhrani/

Vinay G. Sakhrani

September 8, 2006

Date